

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

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INTRACELLULAR THERAPIES, )  
INC., )  
 )  
Plaintiff, )  
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 )  
v. ) Civil Action No. 1-17-cv-00776  
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JOSEPH MATAL, )  
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 )  
Defendant. )  
)

MEMORANDUM OPINION

THIS MATTER comes before the Court on Plaintiff's Motion for Summary Judgment and Defendant's Cross Motion for Summary Judgment. This action arises from Plaintiff's challenge of the United States Patent and Trademark Office's ("USPTO") patent term adjustment determination for United States Patent No. 8,648,077 (the "'077 patent").

When calculating the term of a patent, the USPTO is required to account for statutorily enumerated delays in the USPTO's examination of the patent application as well as any amount of time "during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2)(C)(i). To prevent a patent term's loss of

time due to delay caused by the USPTO, the statutory 20-year patent term is to be extended by the sum of USPTO delay time minus applicant delay time. This calculation is referred to as a patent term adjustment ("PTA").

Plaintiff Intra-Cellular Therapies, Inc. is the owner and assignee of all right, title, and interest in the '077 patent. The '077 patent was issued on February 11, 2014. In calculating the PTA for the '077 patent, the USPTO issued a Final Decision on January 9, 2017, maintaining a determination of 264 days of PTA. This PTA calculation was based in part on a finding of 142 days of Applicant's delay during the prosecution. This 142 day delay period was the sum of four distinct periods of Applicant's delay: (1) a 90-day period of delay under 37 C.F.R. § 1.704(b); (2) a 10-day period of delay under 37 C.F.R. § 1.704(c)(10); (3) a 21-day period of delay under 37 C.F.R. § 1.704(c)(10); and (4) a 21-day period of delay under 37 C.F.R. § 1.704(b). In this action, Plaintiff challenges only the fourth period of Applicant's delay. This 21-day period of delay was calculated under 37 C.F.R. § 1.704(b) with respect to Plaintiff's responses to the USPTO's Final Office Action of April 17, 2013 (the "Final Office Action"), and Advisory Action of July 26, 2013 (the "Advisory Action").

The dispute between the parties revolves around whether the Plaintiff properly "replied" to the USPTO's final rejection of

the '077 patent application, which was communicated in the Final Office Action. The USPTO determined that Plaintiff failed to properly "reply" within the statutorily-defined three month period allowed for reply. Plaintiff, conversely, contends that it did submit a timely and proper reply on July 17, 2013 (the "July 17, 2013 submission"), and that the USPTO erred when it determined that the July 17, 2013 submission was not a proper reply. The USPTO argues that the July 17, 2013 submission was not a proper reply because it failed to place the '077 patent application in condition for allowance, or, in the alternative, because it was a "reply having an omission," and thus the USPTO's decision to assess applicant delay until Plaintiff corrected the omissions present in the July 17, 2013 submission was not arbitrary and capricious.

Plaintiff filed this case on July 7, 2017, under 35 U.S.C. § 154(b)(4)(A), the Administrative Procedures Act, and the Fifth Amendment of the U.S. Constitution. Plaintiff then filed a Motion for Summary Judgment on October 2, 2017, arguing that there is no dispute of material facts as to the dates or content of the relevant office actions and responses thereto, and therefore the only issues to be resolved are issues of law. The USPTO filed a Cross Motion for Summary Judgment on October 25, 2017, arguing that because the APA "confines judicial review of executive branch decisions to the administrative record of

proceedings before the pertinent agency[,] . . . there can be no genuine issue of material fact in an APA action, and the legal questions presented in [an APA] action are therefore ripe for resolution on cross-motions for summary judgment." Genetics & IVF Inst. v. Kappos, 801 F. Supp. 2d 497, 502 (E.D. Va. 2011).

Under Federal Rule of Civil Procedure 56, a court should grant summary judgment if the pleadings and evidence show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). In reviewing a motion for summary judgment, the court views the facts in the light most favorable to the non-moving party. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Once a motion for summary judgment is properly made, the opposing party has the burden to show that a genuine dispute of material fact exists. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986). The Court finds there is no genuine dispute of material fact and this case is ripe for summary judgment.

Under the APA, a "reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5. U.S.C. § 706(2)(A). This standard "is the most deferential of the APA standards of

review, and is only met where a reviewing court can conclude with definite and firm conviction that a clear error of judgment or a mistake has been committed." President & Fellows of Harvard Coll. v. Lee, 589 F. App'x 982, 984 (Fed. Cir. 2014).

The statute relevant to PTA calculation is 35 U.S.C. § 154(b). This statute defines applicant delay as "the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application." 35 U.S.C. § 154(b)(2)(C)(i). One such failure to engage in reasonable efforts occurs when an applicant takes longer than three months to respond to a notice from the USPTO. Id. § 154(b)(2)(C)(ii). Further, the statute instructs the USPTO Director to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments." Id. § 154(b)(3)(A). The Director is instructed to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." Id. § 154(b)(2)(C)(iii). The USPTO has accordingly promulgated regulations pursuant to that authority. 37 C.F.R. §§ 1.702-04.

Two of these regulations, §§ 1.702 and 1.703, describe the grounds for assessing examination delay. Id. at §§ 1.702-03. Section 1.704(a) then provides for PTA to be reduced by any period of applicant delay, and § 1.704(b) explains that any

period of time in excess of three months taken by the applicant to reply to any notice or action by the USPTO making any rejection, objection, argument, or other request is assessed as applicant delay. Id. at § 1.704. Finally, § 1.704(c) provides a list of "exemplary circumstances that constitute" applicant delay, noting that the USPTO could also reduce the period of adjustment on a case-by-case basis for "conduct that interferes with the Office's ability to process or examine an application . . . even if such conduct is not specifically" listed in 1.704(c). Id.

On April 17, 2013, the USPTO issued a final action rejecting the application for the '077 patent. Specifically, of the thirty-one claims that were still pending in the application, ten claims were withdrawn, thirteen claims were objected to, and eight claims were rejected. No claims were allowed. Admin. R. at 281-97 (Dkt. No. 12).

On July 17, 2013, exactly three months after the issuance of the USPTO's final action, Plaintiff filed an amendment in response to the final action. Id. at 306-29. Plaintiff amended the majority of the claims in an effort to overcome the examiner's objections and rejections; however, it also presented arguments as to certain of the examiner's objections and rejections, and it added one new claim. Id. at 319-20.

On July 26, 2013, the USPTO issued an Advisory Action, which indicated that the July 17, 2013 submission failed to overcome all of the rejections of record. Five claims remained rejected, Claim 34 was objected to based on an informality, and seventeen claims remained objected to based on their dependency on a rejected claim. The Advisory Action stated that the time period in which to file a compliant reply to the final rejection continues to run from the mailing date of the final rejection. Id. at 331-32.

On August 7, 2013, Plaintiff filed a supplemental amendment, which cancelled and further amended claims to finally overcome all of the examiner's outstanding objections and rejections. Id. at 334-65. On August 20, 2013, the USPTO issued a Notice of Allowance regarding the application for the '077 patent. Id. at 366-78. The '077 patent was ultimately issued thereafter on February 11, 2014.

In calculating PTA, the USPTO assessed 21 days of applicant delay from July 17, 2013 (three months after the final action issued on April 17, 2013), until August 7, 2013, after determining that Plaintiff's July 17, 2013 submission was not a proper reply and that Plaintiff had failed to engage in reasonable efforts to conclude prosecution of the patent until Plaintiff filed its supplemental amendment on August 7, 2013. Id. at 494.

The USPTO's Final Agency Decision found that the July 17, 2013 submission was not a proper reply because, as indicated by the Advisory Action, the submission "fail[ed] to overcome all the rejections of record," and the Advisory Action "object[ed] to new claim 34 based on an informality." Id. Thus, the "July 17, 2013 submission includes an omission in so far as the submission fails to place the application in condition for allowance. In other words, the submission fails to constitute a proper reply to the final Office action." Id. at 495. The USPTO also explained that even if the July 17, 2013 submission were considered a reply under the relevant regulations, it was a reply containing an omission that was not corrected until the August 7, 2013 reply. Id. at 496.

Since this case involves the USPTO's interpretation of 35 U.S.C. § 154, the analysis is guided by the two-step framework set forth in Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837 (1984). The first step of this framework "asks whether Congress directly addressed the precise question at issue." Gilead Scis., Inc. v. Lee, 778 F.3d 1341, 1346 (Fed. Cir. 2015). "Absent a clearly expressed legislative intention to the contrary, the statute's plain language must ordinarily be regarded as conclusive." Id. at 1347.

Here, the question at issue is whether a submission filed after a final Office action that fails to place the application

in condition for allowance (such as the July 17, 2013 submission) constitutes a "fail[ure] to engage in reasonable efforts to conclude prosecution." 35 U.S.C. § 154(b)(2)(C). Plaintiff argues that the plain language of § 154(b)(2)(C) answers this question, suggesting that a submission which substantially advances prosecution amounts to "reasonable efforts to conclude prosecution," even if the submission does not actually place the application in condition for allowance. However, nothing in the plain language of the statute indicates that "reasonable efforts to conclude prosecution" should be read to include an incomplete submission which fails to place the application in condition for allowance, but in some manner advances it closer to allowance. In fact, the Federal Circuit has held that "the statute's 'reasonable efforts' language focuses on applicant conduct as opposed to the results of such conduct." Gilead Scis., Inc., 778 F.3d at 1347. Thus, the plain language of § 154(b)(2)(C) does not answer the question at issue.

Having answered step one of the Chevron framework, the analysis must now proceed to step two. Gilead Scis., 778 F.3d at 1349. The question in step two is whether the agency's answer to the "precise question at issue" is based on a "permissible construction of the statute." Id. (citing Chevron, 467 U.S. at 842-43). The agency's construction of the statute is afforded

substantial weight at this stage of the analysis. "Chevron teaches that when Congress explicitly leaves a gap for an agency to fill, such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute." Id.

Here, Congress has in fact left a gap in § 154 for the USPTO to fill, by delegating to the USPTO the authority to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application." 35 U.S.C. § 154(b)(2)(C)(iii). The USPTO exercised this Congressionally-delegated authority by promulgating 37 C.F.R. § 1.704(b) and 37 C.F.R. § 1.704(c)(7). Thus, both of these regulations are entitled to deference under Chevron. The USPTO interpreted § 1.704(b) and § 1.704(c)(7) together to indicate that "fail[ure] to engage in reasonable efforts to conclude prosecution" includes a reply to a final Office action that does not place the application in condition for allowance, such as Plaintiff's July 17, 2013 submission. Under the Auer deference standard, the USPTO's "interpretation of its own regulation[s] controls, unless the interpretation is 'plainly erroneous or inconsistent with the regulation[s].'" Hudgens v. McDonald, 823 F.3d 630, 638 (Fed. Cir. 2016) (quoting Auer v. Robbins, 519 U.S. 452, 461 (1997)).

Section 1.704(b) states that an applicant may not take more than three months to "reply to any notice or action by the Office making any rejection, objections, argument, or other request," and § 1.704(c)(7) refers to a reply "having an omission." Thus, under the USPTO's interpretation of these two regulations, a "fail[ure] to engage in reasonable efforts to conclude prosecution" includes a reply that omits resolving even one "rejection, objection, argument, or other request" contained in an Office action. Although Plaintiff argues that the USPTO has misapplied these regulations in reaching this conclusion, its arguments fail to establish that the USPTO's interpretation is plainly erroneous, and thus does not overcome Auer deference.

Plaintiff first argues that the USPTO erred when it equated a "reply" under 37 C.F.R. § 1.113 with a "reply" under 37 C.F.R. § 1.704(b) in its Final Agency Decision. Specifically, Plaintiff argues that § 1.113 concerns only the "sufficiency" of a reply, while § 1.704(b) concerns only the "timeliness" of a reply. However, § 1.704(b) references and relies upon § 1.703, by stating that "the period of adjustment set forth in § 1.703 shall be reduced by the number of days" in excess of three months that are taken for an applicant to submit a "reply" to a final Office action. 37 C.F.R. § 1.704(b). Section 1.703, in turn, provides the method of calculating the proper length of a patent term adjustment, including by counting "[t]he number of

days, if any, in the period beginning on the day after the date that is four months after the date a reply in compliance with § 1.113(c) was filed and ending on the date of mailing of either an action under 35 U.S.C. § 132, or a notice of allowance under 35 U.S.C. § 151, whichever occurs first." 37 C.F.R. § 1.703(a)(3). Thus, the PTA calculation explicitly relies in part on whether a "reply" complies with § 1.113(c), and thus a "reply" under § 1.704(b) is therefore inextricably linked with § 1.113(c), and a "reply" under § 1.704(b) must meet the requirements of § 1.113(c).

Looking then to § 1.113(c), that regulation states that a "[r]eply to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim. If any claim stands allowed, the reply to a final rejection or action must comply with any requirements or objections as to form." 37 C.F.R. § 1.113(c). In other words, a proper reply under § 1.113(c) to a final Office action must resolve all rejections or objections, otherwise it does not stop the three-month clock for assessing applicant delay. Because Plaintiff's July 17, 2013 submission did not cancel all of the rejected claims or remove all of the outstanding objections identified in the final Office action, the USPTO determined that the submission was not a proper reply under § 1.113(c), and was

therefore not a "reply" as defined in § 1.703(a)(3) and as incorporated into § 1.704(b).

Plaintiff next argues that "by fully entering the amendments presented in [the July 17, 2013 submission], the PTO effectively conceded that the response was valid." Plaintiff here relies on several passages from the Manual of Patent Examination Procedure ("MPEP"), particularly § 714.03, which states that "[a]mendments after final are approved for entry only if they place the application in condition for allowance or in better form for appeal." However, this section provides two distinct purposes for entering amendments after a final rejection: either because the application has been placed in better condition for allowance, or to place the application "in better form for appeal." Here, the Advisory Action specifically states that "[f]or purposes of appeal, the proposed amendment(s) will be entered." Admin. R. at 331. The determination that entering the amendments would place the application in better form for appeal has no bearing on whether the reply was proper under § 1.704(b).

The USPTO determined that Plaintiff's July 17, 2013 submission was not a valid reply under § 1.703(b), and therefore constituted a "fail[ure] to engage in reasonable efforts to conclude processing or examination" under § 1.704(b). This Court finds that the USPTO's determination was based on a permissible

construction of the relevant statutes, and therefore should be afforded deference under Chevron. Furthermore, this Court finds that the USPTO did not concede that the July 17, 2013 submission was a valid reply in compliance with § 1.113(c) by entering the amendments presented in the submission. Accordingly, the USPTO's Final Decision that the July 17, 2013 submission did not stop the clock under § 1.703(b) for accruing applicant delay was not arbitrary and capricious, and should be affirmed.

For the foregoing reasons, this Court finds that summary judgment should be granted in favor of Defendant. An appropriate order shall issue.

Claude M. Hilton  
CLAUDE M. HILTON  
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia  
February 13, 2018